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| APPLICATION NO. | APPLICATION NO. FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------------|---------------------|----------------------|---------------------------------|------------------|
| 09/717,894 11/21/2000 | | Karl-Heinz Buettgen | C 2109 COGG | 2009 | |
| 23657 | 7590 | 08/26/2003 | | | |
| COGNIS C | | | EXAMINER | | |
| 2500 RENAISSANCE BLVD., SUITE 200 GULPH MILLS, PA 19406 | | | U | MARX, IRENE | |
| | | | | ART UNIT | PAPER NUMBER |
| | | | | 1651 DATE MAILED: 08/26/2003 | 18 |

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 18

Application Number: 09/717,894 Filing Date: November 21, 2000 Appellant(s): BUETTGEN ET AL.

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/2/03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

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(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,753,473

GATFIELD

5-1998

4,608,202

LEPPER et al.

8-1986

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1 through 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gatfield *et al.* taken with Lepper *et al.*

The claims are drawn to a method of producing deacidified fats and/or oils comprising treating a triglyceride having an acid number between 0 and 60 with a lower alcohol and with a lipase and treating the product again with a lower alcohol and lipase, thereby producing a product having a lower acid number from about 0.1 to about 0.5.

Gatfield *et al.* disclose a method of treating Stillingia oil, a triglyceride, with a lower alcohol, ethanol, to produce a product comprising ethyl esters of trans-2-cis-4-decadienoic acid and other ethyl esters, such as esters of linolenic acid (See, e.g., Table 1) using *C. antarctica*

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lipase as the catalyst. The reaction temperature is disclosed to be between 20 and 60°C (col. 2, line 47). At least in Example 4, the concentration of lipase is 5% by weight of the triglyceride.

The reference differs from the claimed invention in that neither the starting acid number of the oil nor the final acid number of Stillingia oil is indicated. However, it is recognized in the art that vegetable oils, such as Stillingia oil, a vegetable oil obtainable from the fruit of the tallow tree, are not fully esterified and have acid numbers between 10 and 40 depending on the quality. Should Stillingia oil be considered a "commercial grade tallow", it would have an acid value of 30-40 (See, e.g., Lepper col. 1, lines 19-35). Thus, one of ordinary skill in the art would reasonably have expected that at least some free fatty acids are present in Stillingia oil. Accordingly, one of ordinary skill in the art would reasonably have concluded that the reactions disclosed in the Examples in Gatfield *et al.* are esterification reactions at least to some extent and that pre-esterification products having a lower acid number result from the reaction. See, e.g., Example 2, wherein *C. antarctica* lipase is used. It is noted that the proportion of transesterified product, if any, is very low.

It is also of interest to note that Gatfield *et al.* discloses that lipase B is suitable for esterification in the "reaction of coconut fat with ethanol in the presence of lipase B" wherein ethyl caprylate and ethyl caprate are produced in good yields. (See, e.g., col. 1, lines 55-60). This esterification process is the same as step a) in the presently claimed process. Since it is an esterification process, the acid value of coconut fat would reasonably be expected to be lowered at least to some extent in the resulting pre-esterified product obtained.

In addition Lepper *et al.* discloses that the esterification of a vegetable oil such as coconut oil with a short chain monoalcohol using a suitable catalyst will result in a product having a lower acid value. See, example 1, wherein coconut oil is reacted with methanol in the presence of a chemical catalyst. The substitution of an effective enzymatic catalyst for the chemical catalyst in the reaction would reasonably have been expected by one of ordinary skill in the art to result in substantially similar, if not the same, reaction products having a lower acid number. In addition, Lepper *et al.* indicates the desirability of carrying out both stages of the combination of preliminary esterification of the free fatty acids with transesterification at comparatively low temperatures and without using high pressure (col. 2, lines 23-29), which strongly suggests and

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provides compelling motivation for the substitution an enzymatic catalyst and process for the harsher chemical process.

The Gatfield *et al.* reference differs from the invention as claimed in that the lipase is disclosed to be recycled to treat the original substrate rather than the pre-esterification product. However, as noted, the esterification of free fatty acids occurs at least to some extent, and these esterified products would be expected to be transesterified in the second and successive rounds of reaction. In any event, it is clear from the reference that the lipase may be recycled. See, e.g., col. 2, lines 61-63. Furthermore, in the process of Lepper *et al.* the pre-esterified product is subjected to further esterification with the alcohol in a transesterification reactions (See, e.g., Example 1).

Thus, one of ordinary skill in the art would have reasonably expected at the time the claimed invention was made that the reaction of a fat or oil with a lipase and a lower alcohol having an acid number of up to 60, such as coconut oil or Stillingia oil would result in a preesterification product, i.e., an ester or mixtures thereof, suitable for transesterification, using a lipase with similar results, as those disclosed by Lepper *et al.*, since the reactions are substantially similar and differ only in the catalyst used. It is emphasized that the Lepper *et al.* reference uses coconut oil, albeit with a chemical catalyst, and that Gatfield *et al.* disclose the suitability of coconut oil to produce pre-esterified products (See, e.g., col. 1, lines 55-60) and teaches the use of lipase from *C. antarctica* for similar reactions (See, e.g., col. 2, line 10 and Example 2).

With respect to the concentration range of alcohol, the Gatfield *et al.* reference uses a concentration of 20% ethanol, which clearly corresponds to the "excess" required in claim 1. Moreover Lepper *et al.* explains that the quantity of alcohol used has a positive effect on the velocity and completeness of the esterification of the free fatty acids in the esterification process. However, due to the cost of the alcohol, the reference recommends curtailing the amount of alcohol (Col. 6, lines 39-51). Therefore, the use of 1-10% lower alcohol rather than 20% would have been a *prima facie* obvious adjustment to one of ordinary skill in the art at the time the claimed invention for economic reasons, in view of the reference teachings. Also the amount of alcohol used would reasonably be expected to be adjusted depending on the oil or fat substrate, the alcohol and the lipase used in the process.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Gatfield *et al.* by subjecting the preesterification product to further lipase treatment in the presence of ethanol or another alkanol for the expected benefit of maximizing the concentration of valuable esterified products and reducing the acid value of the mixture, as suggested by the teachings of Lepper *et al.*.

Thus, the claimed invention as a whole was clearly <u>prima facie</u> obvious, especially in the absence of evidence to the contrary.

(11) Response to Argument

Appellants urge that the rejection of claims 1 through 10 under 35 U.S.C § 103 is improper, because none of the references relied upon either alone or in combination contain the requisite teaching or suggestion to render the claimed invention *prima facie* obvious.

It is submitted that Appellants' arguments are not persuasive of error in the Examiner's position because the process of Gatfield is directed to the reaction of a triglyceride substrate comprised by the claimed invention with an effective amount of a lipase as the catalyst, including *Candida antarctica* lipase, the same enzyme as used by appellants, in a substantially similar process. The claims are not directed to coconut oil as a substrate, except in dependent claim 4.

The crux of appellants' argument is that the process of Gatfield is a transesterification rather than an esterification reaction. However, appellants fail to consider that Stillingia oil is comprised of free fatty acids at least to some extent, which would naturally be esterified in the process, by the reaction of the free fatty acids with the alcohol (Brief, page 3, paragraph 2).

Moreover, even though Gatfield *et al.* admittedly is directed to modification of Stillingia oil, the reference does disclose the esterification of fatty acids in coconut oil in the background of the invention with lipase as the catalyst and esters as the product. These esters are presumed to be esterified products, in view of the free fatty acid content of the coconut oil as indicated by the teachings in Lepper of free fatty acid content greater that 3% by weight, and an acid number between 10-20 for commercially available coconut oil (See, e.g., col. 1, lines 19-35).

Appellant's argument that Gatfield does not teach the "direct esterification of free fatty acids with lower alkanols such as ethanol in the presence of an enzyme" is confusing, since it is apparent from Lepper *et al.* that vegetable oils and tallow contain free fatty acids, which would

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be directly esterified. The claims as written fail to exclude transesterification, since they are drafted in terms of the open language "comprising".

Appellant's arguments regarding the unpredictability of enzymes in the esterification process taught by Lepper are incorrect. Gatfield indicates in the background of the invention that coconut oil is known to be esterified by lipase B. See, e.g., col. 1, lines 57-60. Therefore, the reaction of coconut oil with lipase for esterification purposes is not unpredictable. Moreover, the arguments presented are inconsistent with the invention as claimed, directed to the use of any lipase, except for claim 8, wherein any triglyceride is reacted. In addition, the specification at bridging paragraph between pages 4 and 5 acknowledges that the use of lipases for the esterification of fatty acids with alcohols is well known. Gatfield recommends the use of precisely the same lipase as Appellant uses in the Examples and in claim 8, i.e. the lipase from Candida antarctica, including NOVOZYM^R 435.

Appellant also argues that the Examiner has failed to show that Gatfield and/or Lepper suggests reacting the pre-esterification product with additional alcohol to form a product having an acid value about 0.1 to about 0.5. In this regard it is noted that at least Lepper *et al.* indicates that in the esterification stage the acid number of the oil or fat is reduced to values of the order of 1 or lower under fairly mild conditions (col. 3, lines 25-39). This step is followed by a transesterification step which would have reasonably been expected to lower the acid value even further (col. 3, lines 51-55). In addition, the touted results are obtained in the instant specification only in Examples 1 and 2. In these Examples a specific enzyme, the lipase from *Candida antarctica*, NOVOZYM^R 435, is used to bioconvert a specific substrate, crude coconut oil with an acid value of 8.2, under specific process conditions. This is not the invention claimed.

On the one hand, Appellant's argue that the process of Lepper et al. is directed solely to a transesterification process (Brief, page 4, line 21 et seq.). On the other hand, Appellant explains that the process of Lepper et al. is directed to a process of making fatty acid esters by first forming a preliminary ester by reacting a fatty acid with an aliphatic alcohol in the presence of a catalyst. This argument is clearly inconsistent and contradictory. The process described at Brief, page 5, paragraph 2) is the same esterification/transesterification process as claimed, albeit using chemical catalysts. As noted supra, the disclosure of Gatfield suggests esterification of coconut oil with lipase, and, even though Gatfield is interested in a specific aspect of the treatment of the

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triglyceride Stillingia oil with lipase, the reaction of interest, i.e. esterification of free fatty acids in the oil, also occurs naturally upon contact of the oil with alcohol and enzyme, which results in the lowering of the acid number of the Stillingia oil, whether Gatfield is interested in this result or not.

With respect to the arguments that the optimization of substrate, alcohol and lipase concentration are not properly addressed, it is noted that only in dependent claims are specific reaction parameters required. Moreover, the reaction temperature in Gatrield is disclosed to be between 20 and 60°C (col. 2, line 47), which is within the claimed range, and the concentration of lipase in Gatfield is about 5% by weight of the triglyceride at least in Example 4. With respect to the concentration range of alcohol, the Gatfield *et al.* reference uses a concentration of 20%, which clearly corresponds to the "excess" required in claim 1. Moreover Lepper *et al.* explains that the quantity of alcohol used has a positive effect on the velocity and completeness of the esterification of the free fatty acids in the esterification process. However, due to the cost of the alcohol, the reference recommends curtailing the amount of alcohol (Col. 6, lines 39-51). Therefore, the use of 1-10% lower alcohol rather than 20% would be have been a *prima facie* obvious adjustment to one of ordinary skill in the art at the time the claimed invention for economic reasons, in view of the reference teachings.

Therefore, it is deemed that the strong <u>prima facie</u> case of obviousness has not been rebutted, since no evidence has been presented to show the distinguishing features between the presently claimed process and the process of the references taken as a whole.

Conclusion

Accordingly, it is considered that claims 1 through 10 on appeal are unpatentable for being obvious as a whole to one of ordinary skill in the art at the time the claimed invention was made, as established by the references, and Appellants' arguments and evidence fail to persuade otherwise. Therefore, it is submitted that the decision of the Examiner is sound and should be sustained.

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Respectfully submitted,

Yhree Marx

Irene Marx

Primary Examiner

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July 31, 2003

Conferees Michael Wityshyn, SPE Christopher Low, SPE

COGNIS CORPORATION 2500 RENAISSANCE BLVD., SUITE 200 GULPH MILLS, PA 19406 Michael G. Wilyshyn
Supervisory Patent Examiner
Technology Center 1600

Christopher S. J. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800

| | Application No. | Applicant(s) | | | | | |
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| Interview Summary | 09/717,894 | BUETTGEN ET | AL. | | | | |
| | Examiner | Art Unit | | | | | |
| | Irene Marx | 1651 | | | | | |
| All participants (applicant, applicant's representative, PTO | personnel): | | | | | | |
| (1) <u>Irene Marx</u> . | (3) | | | | | | |
| (2) <u>Mr. Trzaska</u> . | (4) | | ٠ | | | | |
| Date of Interview: 23 June 2003. | | | | | | | |
| Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant 2 |)⊡ applicant's representative |] | | | | | |
| Exhibit shown or demonstration conducted: d) Yes If Yes, brief description: | e)⊠ No. | | | | | | |
| Claim(s) discussed: | | | | | | | |
| Identification of prior art discussed: | | | | | | | |
| Agreement with respect to the claims f) was reached. g) | ⊠ was not reached. h) N/ | A. | | | | | |
| Substance of Interview including description of the general reached, or any other comments: Acknowledged receipt of to the specific oil, i.e., coconut oil, and the specific enzyme use the specific temperature and time frame in the examples prosince the coverage provided would be too narrow. (A fuller description, if necessary, and a copy of the amendmallowable, if available, must be attached. Also, where no copallowable is available, a summary thereof must be attached.) THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACINTERVIEW. (See MPEP Section 713.04). If a replicate the content of the section 713.04. | ne appeal brief and informed a used, i.e. Candida antarctica liperide for patentable subject materials which the examiner agree by of the amendments that wo | applicant that classes, in combinated atter. Applicant of the classes would render the classes at the classes a | ims relating ation with declined, the claims aims | | | | |
| INTERVIEW. (See MPEP Section 713.04). If a reply to the la GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FIL INTERVIEW. See Summary of Record of Interview requirements | ast Office action has already b | een filed, APPLI | | | | | |
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| Examiner Note: You must sign this form unless it is an Attachment to a signed Office action. S. Patent and Trademark Office | Examiner's signatu | re, if required | | | | | |

| | Application No. | Applicant(s) |
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| Interview Summary | 09/717,894 | BUETTGEN ET AL. |
| , | Examiner | Art Unit |
| | Irene Marx | 1651 |
| All participants (applicant, applicant's representative, PT(|) personnel): | |
| (1) <u>Irene Marx</u> . | (3) | |
| (2) <u>Mr. Trzaska</u> . | (4) | |
| Date of Interview: 23 June 2003. | | • |
| Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant | 2) applicant's represent | tative] |
| Exhibit shown or demonstration conducted: d) Yes If Yes, brief description: | e)⊠ No. | |
| Claim(s) discussed: | | |
| Identification of prior art discussed: | | |
| Agreement with respect to the claims f) was reached. | g)⊠ was not reached. h) | □ N/A. |
| reached, or any other comments: Acknowledged receipt of to the specific oil, i.e., coconut oil, and the specific enzymenthe specific temperature and time frame in the examples particle the coverage provided would be too narrow. (A fuller description, if necessary, and a copy of the amendallowable, if available, must be attached. Also, where no callowable is available, a summary thereof must be attached. THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ANTERVIEW. (See MPEP Section 713.04). If a reply to the GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FINTERVIEW. See Summary of Record of Interview requirer. | In used, i.e. Candida antarc rovide for patentable subjections which the examiner opy of the amendments the distribution of the amendments the distribution of the carting | r agreed would render the claims at would render the claims THE SUBSTANCE OF THE ady been filed, APPLICANT IS |
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